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**STATE OF WISCONSIN
Division of Hearings and Appeals**

In the Matter of

██████████
██████████
██████████
██████████

DECISION
Case #: CWA - 206558

PRELIMINARY RECITALS

Pursuant to a petition filed on October 13, 2022, under Wis. Admin. Code § HA 3.03, to review a decision by the Bureau of Long-Term Support regarding Medical Assistance (MA), a hearing was held on December 20, 2022, by telephone. A hearing scheduled for November 30, 2022, was rescheduled at petitioner's request.

The issue for determination is whether the petitioner meet her burden to demonstrate that the IRIS program incorrectly denied her budget amendment request for prolotherapy.

There appeared at that time the following persons:

PARTIES IN INTEREST:

Petitioner:

██████████
██████████
██████████
██████████

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, WI 53703
By: Angela Sutherland
Bureau of Long-Term Support
PO Box 7851
Madison, WI 53707-7851

ADMINISTRATIVE LAW JUDGE:

Jason M. Grace
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner (CARES #) is a resident of Dane County. She is enrolled in the IRIS program, with TMG her IRIS Consultant Agency (ICA).
2. The Long-Term Care Functional Screen dated May 20, 2022, indicates that petitioner meets the target groups of physical disability and developmental disability per the state but not the federal definition. She requires supervision for activities of daily living (ADLs) including bathing, dressing, mobility in home, toileting, and transferring. She requires hands-on care for the instrumental activities of daily living (IADLs) of laundry/chores and supervision for meal preparation.
3. Petitioner has diagnoses that include (but are not limited to): hypothyroid, trochanteric bursitis of left hip, arthropathy of elbow, chronic pain syndrome, chronic neck pain, fibromyalgia, carpal tunnel, generalized anxiety disorder, and osteoarthritis in both knees. She experiences various levels of pain in her knees, spine, neck, and wrists.
4. Petitioner's current IRIS Individual Support and Services Plan (ISSP) has a total annual budget of \$24,148.76, which is divided amongst a health club membership, consumer education and training sessions for trigger point massage therapy, and supportive home care (SHC).
5. Petitioner submitted an IRIS budget amendment (BA) to fund prolotherapy to alleviate pain in her knees.
6. As part of the BA process, the ICA had a Nurse Consultation done to understand prolotherapy. The consultant provided the following information:

Prolotherapy is considered a complementary treatment not regulated or approved by the FDA; therefore, it would be considered experimental in nature. This treatment involves repeated injections of an irritant, such as sugar solution, to a tendon or ligament of the infected joint. Per the Mayo Clinic, there have not been enough studies done to support prolotherapy as an effective and safe treatment option for treating chronic pain. Furthermore, the American Pain Society advises against the use of prolotherapy for treating pain due to the lack of evidence-based studies available. Prolotherapy is not covered under Medicare or Medicaid and would need to be private paid. As chronic pain is a long-term condition, the primary goal is to treat the pain so that it is manageable. The person is encouraged to seek medical treatment and advice from their primary care physician (PCP) and/or pain doctor. The PCP or pain MD can prescribe different treatments available covered under Medicare and Medicaid including physical therapy involving heat or cold therapy, massage, stretching exercises, transcutaneous electrical nerve stimulation (TENS) unit, occupational therapy, and counseling. The person may also find the following activities helpful for managing pain including relaxation techniques, deep breathing and meditation.

Respondent's Exhibit Packet, A1-2.

7. Per a written notice issued September 13, 2022, the Department denied the BA request. The notice provided the following:

The Department has Up-Held the decision to deny the Budget Amendment request for a Counseling and Therapeutic Services. This decision was based on the information provided within the Budget Amendment request form (F-01210). The participant is requesting .23 sessions per week of Prolotherapy. Per the IRIS Nurse,

‘Prolotherapy is considered a complementary treatment not regulated or approved by the Federal Drug Administration (FDA); therefore, it would be considered experimental in nature’. According to the IRIS Policy Manual, ‘Experimental goods or treatments’ are Non-Allowable Services.

After consultation with the IRIS Registered Nurse, the following recommendations were made: “as chronic pain is a long-term condition; the primary goal is to treat the pain so that it is manageable.

- The person is encouraged to seek medical treatment and advice from their primary care physician (PCP) and/or pain doctor. The Primary Care Physician (PCP) or pain Medical Doctor can prescribe different treatments available covered under Medicare and Medicaid that would include physical therapy involving heat or cold therapy, massage, stretching exercises, transcutaneous electrical nerve stimulation (TENS) unit, occupational therapy, or counseling.
- The participant may also find the following activities helpful for managing pain including, relaxation techniques, deep breathing and meditation.

Since the request is a non-allowable service, the request is denied.

Respondent’s Exhibit Packet, B1.

8. Petitioner filed a timely appeal.

DISCUSSION

The IRIS program is a Medical Assistance (MA) home and community-based long term care waiver program authorized under §1915(c) of the Social Security Act. The program permits a state to furnish an array of home and community-based services that assist Medicaid beneficiaries to live in the community and avoid institutionalization. The State has broad discretion to design its waiver program to address the needs of the waivers target population. The waiver approved by the Centers for Medicare and Medicaid Services (CMS) which provides the program’s authority is available at <https://www.dhs.wisconsin.gov/iris/hcbw.pdf>. State policies governing administration of the IRIS program are included in the IRIS Policy Manual (available at <http://www.dhs.wisconsin.gov/publications/P0/P00708.pdf>).

Petitioner submitted a BA request for the IRIS program to fund the cost of prolotherapy to address knee pain. It appears that her standard MA benefits previously denied coverage for the therapy.

The petitioner submitted numerous documents in supports of her appeal. This included what appears to be promotional materials from multiple providers that advocate the benefits of prolotherapy, her own medical records, and letters from three medical doctors who recommended prolotherapy for petitioner. Petitioner also included a summary of what appears to be a study involving prolotherapy for individuals with osteoarthritic finger joints and a 2013 controlled trial for individuals with knee osteoarthritis. Petitioner indicated that the therapy was covered by a friend’s HMO which petitioner would be switching to as of January 1, 2023.

The Department has an obligation to ensure the health and safety of IRIS participants. HCBS Waiver, pg. 7, and IRIS Policy Manual, §6.4. It also has an obligation to implement the IRIS program in a fiscally sound manner; wisely and responsibly respecting the use of public dollars. See, IRIS Policy Manual 1.1D and 5.6A.4. Consistent with those obligations, the Department may only reimburse providers for medically necessary and appropriate health care services and equipment listed in Wis. Stat. §§49.46(2) and 49.47(6)(a), as implemented by Wis. Admin. Code ch. DHS 107. In contrast, it does not cover services the Department finds experimental. See Wis. Admin. Code, § DHS 107.03(4) and IRIS Policy Manual 5.4B, Non-Allowable Services.

When determining whether a service is necessary, the Department must review, among other things, the medical necessity of the service, the appropriateness of the service, the cost of the service, the extent to which less expensive alternative services are available, and whether the service is an effective and appropriate use of available services. Wis. Adm. Code § DHS 107.02(3)(e)1.,2.,3.,6. and 7. “Medically necessary” means a medical assistance service under ch. DHS 107 that is:

- (a) Required to prevent, identify or treat a recipient's illness, injury or disability; and
- (b) Meets the following standards:
 1. Is consistent with the recipient's symptoms or with prevention, diagnosis or treatment of the recipient's illness, injury or disability;
 2. Is provided consistent with standards of acceptable quality of care applicable to the type of service, the type of provider, and the setting in which the service is provided;
 3. *Is appropriate with regard to generally accepted standards of medical practice;*
 4. Is not medically contraindicated with regard to the recipient's diagnoses, the recipient's symptoms or other medically necessary services being provided to the recipient;
 5. *Is of proven medical value or usefulness and, consistent with s. DHS 107.035, is not experimental in nature;*
 6. Is not duplicative with respect to other services being provided to the recipient;
 7. Is not solely for the convenience of the recipient, the recipient's family, or a provider;
 8. With respect to prior authorization of a service and to other prospective coverage determinations made by the department, is cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient; and
 9. Is the most appropriate supply or level of service that can safely and effectively be provided to the recipient.

Wis. Admin. Code, § DHS 101.03(96m) (*emphasis added*). It is paragraphs 3 and 5 from the above provision that are at issue here.

It is a well-established principle that a moving party generally has the burden of proof, especially in administration proceedings. *State v. Hanson*, 295 N.W.2d 209, 98 Wis. 2d 80 (Wis. App. 1980). In a case involving a BA request, the IRIS participant bears the burden to prove the requested service meets approval criteria. Here, petitioner has the burden to establish that the Department incorrectly denied her BA request for prolotherapy.

The Department's position is that prolotherapy is "experimental." That conclusion appears to have been reached during a review by a single IRIS nurse of the information reflected in Finding of Fact 6 above. The record, however, does not indicate that the Department's review in making that determination was as envisioned in Wis. Admin. Code, §DHS 107.035. That being the case, the petitioner still bears the burden to demonstrate that prolotherapy meets criteria for approval.

It was not disputed that prolotherapy is not FDA approved, and that it is not covered under standard MA and Medicare. Moreover, literature from the Cleveland Clinic that was provided by petitioner indicated that most studies have found no scientifically provable benefits and experts have not proven the success rate of prolotherapy in a scientifically significant way. See, Petitioner's Exhibits, Cleveland Clinic, Prolotherapy: What It Is, Uses & Side Effects. This is consistent with the information found during the Nurse Consultation as to the lack of studies that support prolotherapy as an effective and safe treatment option for treating chronic pain, along with the guidance from the American Pain Society against the use of prolotherapy for treating pain due to the lack of evidence-based studies. See, Findings of Fact 6.

Based on the record, I do not find that petitioner has demonstrated that prolotherapy is "appropriate with regard to generally accepted standards of medical practice" and "...of proven medical value or usefulness..." See, DHS 101.03(96m) 3 and 5, above. As such, I must find that petitioner failed to meet her burden to demonstrate that the IRIS program incorrectly denied her BA request for funding of prolotherapy.

CONCLUSIONS OF LAW

The petitioner failed to meet her burden to demonstrate that the IRIS program incorrectly denied her budget amendment request for funding of prolotherapy.

THEREFORE, it is

ORDERED

That petitioner's appeal is dismissed.

REQUEST FOR A REHEARING

That this appeal is dismissed.

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 4822 Madison Yards Way, 5th Floor North, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

APPEAL TO COURT

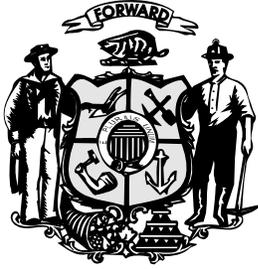
You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, **and** on those identified in this decision as “PARTIES IN INTEREST” **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Madison,
Wisconsin, this 20th day of January, 2023



Jason M. Grace
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

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The preceding decision was sent to the following parties on January 20, 2023.

Bureau of Long-Term Support

